Complete Summary

GUIDELINE TITLE

Management of regional lymph nodes in melanoma. In: Clinical practice guidelines for the management of melanoma in Australia and New Zealand.

BIBLIOGRAPHIC SOURCE(S)

Management of regional lymph nodes in melanoma. In: Australian Cancer Network Melanoma Guidelines Revision Working Party. Clinical practice guidelines for the management of melanoma in Australia and New Zealand. Wellington (NZ): The Cancer Council Australia, Australian Cancer Network, Sydney and New Zealand Guidelines Group; 2008. p. 79-85. [16 references]

GUIDELINE STATUS

This is the current release of the guideline.

The National Health and Medical Research Council (NHMRC) and New Zealand Guidelines Group (NZGG) expect that all guidelines will be reviewed no less than once every five years. Readers should check with the Australian Cancer Network or NZGG for any reviews or updates of these guidelines.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Invasive melanoma (metastasis to the regional lymph nodes)

GUIDELINE CATEGORY

Counseling
Management

Risk Assessment
Treatment

CLINICAL SPECIALTY

Dermatology
Nuclear Medicine
Oncology
Pathology
Radiation Oncology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To assist clinicians who care for patients with melanoma
- To assist in raising standards and producing greater uniformity of care by specifying evidence-based protocols for the prevention, diagnosis, treatment, and follow-up of melanoma

TARGET POPULATION

All children and adults with melanoma in Australia and New Zealand

INTERVENTIONS AND PRACTICES CONSIDERED

Management/Treatment

1. Discussion with patient about therapeutic options
2. Sentinel lymph node biopsy
3. Completion lymphadenectomy
4. Therapeutic lymph node dissection
5. Referral to specialist center
6. Follow-up

MAJOR OUTCOMES CONSIDERED

- Surgical morbidity
- Accuracy of procedure
- Survival rates (5 year, overall)
- Rate of distant metastasis
- Risk of recurrence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Develop a Search Strategy

A search strategy based on the PICO (populations, interventions, comparisons, outcomes) was developed for each research question. A generic search strategy for â☐˜melanoma´ was used by most chapter groups, and additional limits were imposed with regard to patients, interventions, comparisons, outcomes or other relevant aspects. Keywords were devised for each search following discussion with the chapter leader(s) during the PICO process. Additional sources for keywords and MeSH or subject terms were determined by searching other relevant evidence-based clinical guidelines, systematic review articles, and literature pertaining to each question. These terms were then combined into a single systematic search strategy applied to all included electronic databases. For quality control, keywords, MeSH or subject terms, and searches were checked by other members in the chapter group, the University of Sydney´s medical librarian, and an National Health and Medical Research Council representative.

Search the Literature

Literature searching was conducted systematically using electronic databases concluding mid-2006 to early-2007, such as:

- Medline
- EMBASE
- PubMed
- Cinahl
- Cochrane Library
- AUSThealth
- Clinical Evidence
- Psychinfo

Search histories were dated, documented, and are available on request from the Australian Cancer Network or the New Zealand Guidelines Group (www.nzgg.org.nz). The chapter leaders and the methods consultants were asked to provide details on the following:

- Electronic databases searched
- Terms used to search the databases
- Search inclusion/exclusion criteria dates the search included
- Abbreviations
- Methods used to assess the quality of the search
- Language
- Study type

In addition, chapter leaders and their expert groups were asked to hand search the reference lists at the end of their relevant articles to identify additional articles

not identified through searches of the electronic databases. Finally, bi-annual meetings of the guidelines Working Party provided a forum for discussion and sharing of overlapping evidence, and/or discovery of unpublished literature and information from other key organisations.

Select and Sort the Literature

The literature generated by the electronic database searches was appraised for relevance to each question. The following steps were taken to select and sort the literature:

1. Review titles from the search
2. Review abstracts
3. Where uncertain about relevance, download full text of article
4. Identify articles answering the questions and those useful for background information
5. Obtain articles from the Internet, library or interlibrary loans
6. Sort studies by type (e.g., interventions, prognosis, diagnosis)
7. Sort studies by design (e.g., systematic review, randomised controlled trial, cohort, case control, case series, descriptive)
8. Determine whether systematic reviews account for all preceding literature
9. Prepare folders to file searches, background papers and reviewed articles for each question addressed
10. Enter selected articles for review into the guideline master list
11. Assess the quality of the search and the appraisal

All articles emerging from this process as potentially relevant to a guidelines question were forwarded to the chapter leader for his/her consideration and for critical appraisal.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Designations of Levels of Evidence According to Type of Research Question

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
I	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
II	A randomised controlled trial	A study of test accuracy with an independent, blinded comparison with a valid reference standard, among consecutive patients with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive patients with a defined clinical presentation	All or none	All or none	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)
III-2	A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study • Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III–1 evidence	Analysis of prognostic factors amongst untreated control patients in a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: • Non-randomised, experimental trial • Cohort study • Case-control study
III-3	A comparative study	Diagnostic	A	A case-	A comparative

Level	Intervention	Diagnosis	Prognosis	Aetiology	Screening
	without concurrent controls: • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group	case-control study	retrospective cohort study	control study	study without concurrent controls: • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of patients at different stages of disease	A cross-sectional study	Case series

Note: Explanatory notes for this table are outlined in the methods handbook available on request from the Australian Cancer Network or the New Zealand Guidelines Group.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Critical Appraisal and Summary

Relevant articles selected from the search were reviewed and summarised by the chapter leader. Each article was summarised in a template with headings such as the type of study, level of evidence, number and characteristics of patients, type of analysis, outcome measure and results. Each article was then critically appraised with respect to level of evidence, quality of evidence, size of the effect and relevance of the study, and documented in another template.

Details on the templates, rating systems, and criteria for the critical appraisal process, are outlined in the methods handbook available on request from the Australian Cancer Network or the New Zealand Guidelines Group (www.nzgg.org.nz).

Assess the Body of Evidence

The body of literature was assessed by each chapter leader with respect to the volume of the evidence, its consistency, clinical impact, generalisability and applicability. These aspects were graded and documented in a template.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

These guidelines have been developed by the Australian Cancer Network and the New Zealand Guidelines Group.

In 2005, the Australian Cancer Network (ACN) agreed to facilitate a revision of the 1999 *National Health and Medical Research Council (NHMRC) Clinical Practice Guidelines for the Management of Melanoma* based upon advice from melanoma experts across Australia.

A multidisciplinary group comprising clinical experts, a consumer representative and an epidemiologist was convened to develop the guidelines. This group became known as the Guidelines Working Party. Experts from within or outside the Working Party were nominated to become chapter leaders or members of a chapter group. Further experts were added to the Working Party to lead a chapter group when additional topics were proposed at subsequent meetings. Members of the New Zealand Melanoma Reference Group also joined the Working party in 2006 and New Zealand melanoma experts were added as members of chapter groups.

In early Working Party meetings, it became apparent that the guideline development processes required by the NHMRC for national guidelines had changed somewhat since the last set of guidelines were developed. The processes had become much more scientifically rigorous and involved substantially more documentation of the development processes. In addition, several new questions were posed by clinicians in the Working Party that had not been addressed in the 1999 guidelines. In response, the Working Party decided to develop a new set of melanoma clinical practice guidelines incorporating the newer more rigorous processes and including additional topics, rather than just updating the previous guidelines.

The ACN received a grant from the Cancer Institute New South Wales (NSW) to assist in the development of the guidelines. The grant made it possible for the ACN to contract a consultancy group, the Sydney Health Projects Group at the University of Sydney, to assist in the development of project methods and to complete the searches for each chapter of the guidelines. Further assistance in the development of the guidelines was provided by staff of the NSW Melanoma Network and the New Zealand Guidelines Group. The whole process was monitored and assisted by a representative of the NHMRC Guidelines Assessment Register.

Further details of guideline development methods including the specific questions posed, search strategies, inclusion and exclusion criteria and literature appraisal templates for individual chapters are available on request from the Australian Cancer Network or the New Zealand Guidelines Group (www.nzgg.org.nz).

Steps in the Preparation of NHMRC Clinical Practice Guidelines

All the chapter leaders and their expert working group went through the following steps to complete their recommendations. They received considerable assistance for the first four steps of this process from methods consultants, but the great majority of leaders completed their own critical appraisal and assessment of the body of evidence:

1. Structure the research question
2. Develop a search strategy
3. Search the literature
4. Select and sort the literature
5. Critically appraise and summarise each selected article
6. Assess the body of evidence and formulate recommendations

Structure the Research Question

All chapter leaders and their expert working group were asked to contribute key questions to be researched for this set of guidelines. Over 230 questions were submitted to the Working Party for consideration. The Working Party prioritised the questions for systematic review and decided upon a final list of about 70 questions.

All chapter leaders were asked to specify the purpose, scope and target audience for their questions and structure their question according to the PICO (populations, interventions, comparisons, outcomes) formula. Typically, chapter leaders achieved this and specification of a search strategy (see *Description of Methods Used to Collect/Select the Evidence* field above) during a 30-60 minute meeting with a methods consultant.

Formulate Recommendations

Following grading of the body of evidence, chapter leaders were asked to formulate a recommendation that related to the summarised body of evidence. This recommendation also had to be graded as specified in the "Rating Scheme for the Strength of the Recommendations."

Writing the Chapter

All the chapter leaders and their groups were asked to write their guidelines chapter using the following format:

- Background
- Review of the evidence
- Evidence summary with levels of evidence and numbered references
- Recommendation(s) and its grade

- References

Review of the Chapters

The body of evidence and recommendations for each chapter were reviewed by the Working Party and final recommendations agreed by consensus.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations

Grade	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

Good Practice Points

Good practice points are used when the conventional grading of evidence is not possible –these points represent the views of the Guideline Development Group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A complete draft of the guidelines was sent out for public consultation in Australia and New Zealand in October 2007. In Australia, the consultation process included soliciting public review of the document through advertisements in a range of newspapers. In New Zealand, the draft guideline was widely circulated to all individuals and organisations identified by the New Zealand Melanoma Reference Group as having a potential interest in the document. A large conference meeting was also organized for clinicians and other interested parties in February 2008 to outline the major recommendations in the guideline and to provide a forum for further discussion and debate. All feedback received on the draft during the consultation period in Australia and New Zealand and from the conference meeting was reviewed by the Working Party and subsequent changes to the draft agreed by consensus.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the strength of the recommendations (A, B, C, D) and good practice points are provided at the end of the "Major Recommendations" field.

Management of Regional Lymph Nodes in Melanoma

Recommendations

Sentinel Lymph Node Biopsy

C - Patients with a melanoma greater than 1.0 mm in thickness should be given the opportunity to discuss sentinel lymph node biopsy to provide staging and prognostic information.

C - Sentinel lymph node biopsy (SLNB) should be performed only, following a full discussion of the options with the patient, in a unit with access to appropriate surgical, nuclear medicine and pathology services.

Therapeutic Lymph Node Dissection

C - Patients who have positive sentinel lymph node biopsy should be offered completion lymphadenectomy, or be referred to a specialist centre for discussion of further treatment options.

C - Therapeutic node dissection should be offered to all patients with evidence of metastatic nodal disease after excluding stage IV disease using appropriate investigations.

Good Practice Points

- A therapeutic node dissection includes a full levels (I to III) clearance in the axilla. A therapeutic neck dissection may include a superficial parotidectomy as clinically indicated.
- Patients with inguinal node metastases should be considered for clearance of the intra-pelvic iliac and obturator nodes when the staging investigation demonstrates evidence of involvement.
- Elective clearance of the pelvic nodes should be considered when there is gross macroscopic disease in the inguinal node field or there are three or more histologically positive nodes below the level of inguinal ligament.
- Patients with lymph node metastases should be offered discussion with a multidisciplinary team with a view to enrolment in clinical trials.

Definitions:

Recommendation Grades

Grade	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

Good Practice Points

Good practice points are used when the conventional grading of evidence is not possible –these points represent the views of the Guideline Development Group.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate prevention, diagnosis, and management of melanoma

POTENTIAL HARMS

Surgical morbidity

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This document is a general guide to appropriate practice, to be followed subject to the clinician's judgment and the patient's preference in each individual case.
- The guidelines are designed to provide information to assist in decision-making. They are based on the best evidence available at time of compilation. The guidelines are not meant to be prescriptive.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Australian Cancer Network will lead in disseminating the guidelines in Australia and the New Zealand Guidelines Group will oversee the dissemination and implementation of the guidelines in New Zealand on behalf of the Ministry of Health. In both countries this will include a campaign to raise awareness of the new guidelines, with organized media coverage through multiple outlets and an official launch. Widespread dissemination will be achieved through distribution to relevant professional and other interested groups directly and through meetings, conferences, and other Continuing Medical Education (CME) events. A significant effort will be undertaken to have the Guidelines be introduced to senior undergraduate medical students and to encourage the relevant learned Colleges, which are bi-national (surgeons, radiation oncologists and pathologists), to support the Guidelines and to foster integration of the Guidelines into hospital and community practice through resident and registrar educational activity.

The scope of implementation activities will depend on funding available. It is recognized that a planned approach is necessary to overcome specific barriers to implementation in particular settings and to identify appropriate incentives to encourage uptake of guideline recommendations. Implementation of the guideline will require a combination of effective strategies and may include further CME initiatives and interactive learning, the development and promotion of computer assisted decision aids and electronic decision support systems, and the creation of audit and other clinical tools.

IMPLEMENTATION TOOLS

Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Management of regional lymph nodes in melanoma. In: Australian Cancer Network Melanoma Guidelines Revision Working Party. Clinical practice guidelines for the management of melanoma in Australia and New Zealand. Wellington (NZ): The Cancer Council Australia, Australian Cancer Network, Sydney and New Zealand Guidelines Group; 2008. p. 79-85. [16 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008

GUIDELINE DEVELOPER(S)

Australian Cancer Network - Disease Specific Society
New Zealand Guidelines Group - Private Nonprofit Organization

SOURCE(S) OF FUNDING

Australian Cancer Network

New Zealand Guidelines Group

GUIDELINE COMMITTEE

Management of Melanoma Guidelines Working Party

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Party Members: Professor John Thompson (*Chair*) Surgical Oncologist – Sydney; Professor Bruce Armstrong, Epidemiologist – Sydney; Dr Andrew Barbour, Surgeon – Brisbane; Professor Ross Barnetson, Dermatologist – Sydney; Ms Heather Beanland, Consumer – Melbourne; Dr Trevor Beer, Histopathologist – Perth; Dr Mary Brooksbank, Palliative care physician – Adelaide; A/Professor Bryan Burmeister, Radiation Oncologist – Brisbane; A/Professor Phyllis Butow, Psychologist – Sydney; Dr Katherine Clark, Palliative care specialist – Sydney; Dr Max Conway, Ophthalmologist – Sydney; A/Professor Brendon Coventry, Surgeon – Adelaide; A/Professor Diona Damian, Dermatologist – Sydney; Dr Alan Ferrier, Gynaecological Oncologist – Sydney (deceased 23 December 2007); Professor Michael Frommer, Epidemiologist – Sydney; Ms Marianne Griffin, Nurse – Melbourne; Dr Peter Heenan, Histopathologist – Perth; A/Professor Michael Henderson, Surgical Oncologist – Melbourne; Professor Richard Kefford, Medical Oncologist – Sydney; A/Professor John Kelly, Dermatologist – Melbourne; Clinical A/Professor Stephen Lee, Dermatologist – Sydney; Dr Graham Mann, Senior

Medical Researcher – Sydney; Professor Rebecca Mason, Physiologist – Sydney; A/Professor Grant McArthur, Medical Oncologist – Melbourne; Professor William McCarthy, Surgeon – Sydney; A/Professor Scott Menzies, Melanoma Researcher and Clinician – Sydney; Dr Marc Moncrieff, Surgical Fellow – UK; Dr Joseph Ohana, General Practitioner – Sydney; Professor Ian Olver, Medical Oncologist – Sydney; Mr Michael Quinn, Plastic Surgeon – Sydney; Dr Maureen Rogers, Dermatologist – Sydney; Dr Sabe Sabesan, Medical Oncologist – Townsville; Dr Robyn Saw, Surgeon – Sydney; Dr Helen Shaw, Senior research fellow in surgery – Sydney; Dr Michael Sladden, Dermatologist – Launceston; A/Professor Mark Smithers, Surgeon – Brisbane; A/Professor Graham Stevens, Radiation oncologist – Auckland, New Zealand; Dr Jonathan Stretch, Plastic Surgeon – Sydney; Dr Pip Youl, Epidemiologist – Brisbane; Professor Bruce Barraclough AO, Medical Director, ACN – Sydney (until 31 December 2007); Dr Phoebe Holt, Methods Advisor, NSW Melanoma Network – Sydney; Ms Philippa Middleton, NHMRC Guideline Assessment Reviewer – Adelaide; Emeritus Professor Tom Reeve AC CBE, Medical Advisor, ACN/Convenor, Working Party – Sydney

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The development of these clinical practice guidelines has been undertaken by a non-remunerated working party of the Australian Cancer Network and New Zealand Guidelines Group, with further support from the Cancer Institute New South Wales, The Cancer Council Australia and the Clinical Oncological Society of Australia.

Some members have received sponsorship to attend scientific meetings, been supported in the conducting of clinical trials, or have been involved in an advisory capacity by pharmaceutical and biochemical companies. Others have special interests indicated in specific chapters.

ENDORSER(S)

Cancer Council Australia - Disease Specific Society
Cancer Institute New South Wales - State/Local Government Agency [Non-U.S.]
Melanoma Network (Australia) - Disease Specific Society
National Health and Medical Research Council - State/Local Government Agency [Non-U.S.]

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the New Zealand Guidelines Group Web site.

Print copies: In Australia, order through the Australian Cancer Network by e-mailing can@cancer.org.au. In New Zealand, order through Wickliffe by phoning (04) 496 2277, quote order no. HP: 4701.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Melanoma: an aid to diagnosis. A primary care practitioner resource. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2008 Nov. 4 p. Electronic copies: Available in Portable Document Format (PDF) from the New Zealand Guidelines Group Web site.

Print copies (available in NZ) from the New Zealand Guidelines Group Inc., PO Box 10-665, The Terrace, Wellington, New Zealand; Tel: 64 4 471 4188; Fax: 64 4 471 4185; e-mail: info@nzgg.org.nz or through Wickliffe by phoning (04) 496 2277, quote order no. HP: 4700.

PATIENT RESOURCES

The following is available:

- Melanoma. Information for you, your family, whānau and friends. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2008. 16 p. Electronic copies: Available in Portable Document Format (PDF) from the New Zealand Guidelines Group Web site.

Print copies (available in NZ) from the New Zealand Guidelines Group Inc., PO Box 10-665, The Terrace, Wellington, New Zealand; Tel: 64 4 471 4188; Fax: 64 4 471 4185; e-mail: info@nzgg.org.nz or through Wickliffe by phoning (04) 496 2277, quote order no. HP: 4699.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on July 16, 2009. The information was verifed by the guideline developer on October 22, 2009.

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